

REMARKS

This Amendment is responsive to the Office Action of April 1, 2003. Claims 1, 9, 16, 25, 29 and 32 have been amended. Thus, Claims 1-34 are pending in this case. Reexamination and reconsideration are respectfully requested.

CLAIM REJECTIONS – CLAIMS 24 & 30 – § 112

In the Office Action, Claims 24 and 30 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. The Office Action notes that dependent Claims 24 and 30 are directed to a lateral flow immunoassay strip. While this is true, this is not inconsistent with the base claims which recite a “non-immunoassay” detection pad because dependent Claims 24 and 30 are reciting a structure and step, respectively, in addition to the base claims.

As an example and not by way of limitation, a preferred embodiment of such a claimed device and associated method is illustrated in Figures 8 and 9. An immunoassay test strip 420 is disposed in the cassette 400 in addition to the non-immunoassay, contact urinalysis pad included in the strip assembly 10. Therefore, Applicant respectfully submits that Claims 24 and 30 are clear and definite and, for the purposes of examination, it should not be assumed that the “lateral flow immunoassay strip” was intended to be “non-immunoassay” pad.

CLAIM REJECTIONS – CLAIMS 1-6, 8-19, 23-27 & 29-34 – § 102(b)

In the Office Action, Claims 1-6, 8-19, 23-27 and 29-34 were rejected under 35 U.S.C. § 102(b) as being anticipated by Horstman et al. (US 5,006,474). Applicant

respectfully traverses this rejection. Of the rejected claims, Claims 1, 9, 16, 25, 29 and 32 are independent.

Claim 1 is directed to a lateral flow test strip assembly for testing urine that mimics the lateral flow, wicking action of immunoassays without actually using an immunoassay. The lateral flow is provided by a reagent-free absorbent strip that directs the liquid to a contact detection pad. It should be noted that Claim 1 had previously also recited that the non-immunoassay contact urinalysis pad comprises a reagent composition that detects one or more substances upon contact.

While the introductory paragraphs in the Background of the Invention and the Description of Preferred Embodiments of the Invention recite the terms “non-immunological” or “non-biological,” a closer examination reveals that the teaching the reference provides with respect to the reaction zones 40 is that they are “treated with specific analyte reactants.” (col. 6:43-45). The four examples subsequently provided illustrate the chromatographic operation of the device that is characteristic of assays, and particularly, of analyte-binding chemistry.

Unlike Horstman et al., Applicant’s claimed device is not directed to an assay that performs analyte-binding chemistry. Instead, Claim 1 recites that the contact urinalysis pad comprises a reagent composition that detects one or more substances in the urine by contact, as opposed to binding with an analyte. Applicant seeks to mimic the flow and operation of an immunoassay even though the contact urinalysis pad does not function as an immunoassay. Therefore, since the urinalysis pad itself is not a vehicle for wicking, a separate reagent-free strip absorbent strip is employed that is in fluid communication with the contact urinalysis pad. Thus, Applicant has amended the

claims to clarify that the absorbent strip is separate from the contact urinalysis pad, but in fluid communication therewith.

Horstman et al. do not teach or suggest the use of a separate absorbent strip to wick urine to a contact detection pad that is not used for wicking. In other words, Applicant claims a device that mimics the wicking lateral flow action of an immunoassay even though the operative test portion of the device (i.e., the contact urinalysis pad) is not an immunoassay and does not operate as one.

All of the independent claims recite this feature of the contact urinalysis pad comprising a reagent composition adapted to detect for one or more substances upon contact, and the feature of a reagent-free absorbent strip being separate from, but in fluid communication with said pad.

Applicant further submits that the dependent claims recite additional features not found in Horstman et al. For example, dependent Claim 6 recites that the absorbent strip overlaps a portion of the contact urinalysis pad (which is now separate from the absorbent strip as recited in amended Claim 1). Claim 7 recites that the contact urinalysis pad comprises an adulteration pad. These features are lacking in Horstman et al.

Therefore, Applicant respectfully submits that each independent claim is allowable over Horstman et al. Applicant further submits that the dependent claims are allowable over the cited reference for their dependence on allowable independent claims, for the further patentable features recited therein, and for any further grounds as may be recognized by the Examiner.

CLAIM REJECTIONS – CLAIMS 7, 20-22 & 28 – § 103(a)

Claims 7, 20-22 and 28 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Horstman et al. in view of Lappe (5,916,815).

In order to establish a *prima facie* case of obviousness, the prior art reference(s) must, among other things, teach or suggest all the claim limitations. MPEP § 2142. While Lappe may disclose the detection of adulteration as well as the use of a vessel and lid, the combination of Horstman et al. and Lappe nonetheless fails to disclose a reagent-free absorbent strip that is separate from, but in fluid communication with, a non-immunoassay contact detection pad, which pad comprises a reagent composition adapted to detect one or more specific substances upon contact.

Thus, Applicant respectfully submits that Claims 7, 20-22 and 28 are allowable over the proposed combination for their dependence on the respective allowable independent claims, for the further patentable features recited therein, and for any further grounds as may be recognized by the Examiner.

SUMMARY

Based on the above amendments and accompanying remarks, Applicant respectfully submits that all pending claims are in condition for allowance and respectfully requests a Notice of Allowance. Applicants encourage the Examiner to telephone the undersigned attorney if it appears that a telephone conference would facilitate allowance of the application.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

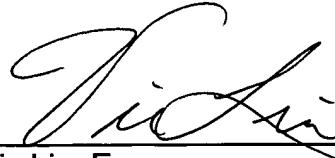
August 1, 2003

by Angela Williams


Signature

August 1, 2003

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